



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Encore Medical, L.P.
Ms. Teffany Hutto
Manager, Regulatory Affairs
9800 Metric Boulevard
Austin, Texas 78758

Re: K100741

Trade/Device Name: Reverse® Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: July 6, 2010
Received: July 7, 2010

Dear Ms. Hutto:

This letter corrects our substantially equivalent letter of August 2, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100741

11/1

510(k) Number (if known): _____

Device Name: Reverse Shoulder Prosthesis

Indications for Use:

AUG 02 2010

**Reverse® Shoulder Prosthesis
Indications for Use**

For treatment of patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jondu J. Jr. Mxm
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100741

Mark H. Mikkelsen

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

K100741
510(k) Number _____

K100741

P-111

Summary of Safety and Effectiveness

Date: July 27, 2010

Contact Person:

Tiffany Hutto

AUG 02 2010

Manager, Regulatory Affairs

Phone: (512) 834-6255

Fax: (512) 834-6313

Email: tiffany.hutto@djosurgical.com

Product	510(k) Number, Clearance Date/ Classification	Product Code
Reverse® Shoulder Prosthesis	K041066 – March 24, 2005 K051075 – May 27, 2005 K092873 – October 27, 2009 Class II	KWS

Product Code	Regulation and Classification Name
KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description: The modification consists of creating a monoblock device by joining the humeral socket with the humeral stem and to add additional humeral insert sizes. There is no change to the intended use or fundamental scientific technology of the RSP with the modifications in this Special 510(k) submission. This includes no changes to packaging or sterilization.

Indications for Use: The RSP is indicated for treatment of patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Predicate Device:

- Reverse Shoulder Prosthesis – K041066, K051075, K092873.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same indications, sterilization, and intended use.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected clinical conditions.

Verification activities were performed to determine if the modifications demonstrate equivalent characteristics to the predicate device. These activities included: geometric analysis for insert articulation, socket lever out strength, stress analysis, tolerance analysis, plasma coating characterization, material properties review, and design comparison. All activities demonstrate that the modified device is substantially equivalent to the predicate.

Clinical Testing: None provided.